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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,415	12/09/2003	Garland L. Segner	5236-000470/US	3933

28997 7590 09/26/2005

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EXAMINER

JOHNSON III, HENRY M

ART UNIT PAPER NUMBER

3739

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/731,415	Applicant(s) SEGNER ET AL.	
	Examiner Henry M. Johnson, III	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>031504</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The continuation information should be serial number 09/771,954, not 09/711,954.

On page 5, paragraph 0037, the text jumps abruptly from figure 2 to labels of figure 4 without mention of the figure.

Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the method steps of claims 24-26 are not included in the specification.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: label 368 (paragraph 0053) is not included in any figure. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same

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invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-26 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-26 of copending Application No. 10/865038. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 27 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,662,034. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30 and 33 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,662,034.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in scope.

Claim Objections

Claim 1 is objected to because of the following informalities: the word spaces in line 4 should be spaced.

Claim 29 is objected to because of the following informalities: the word sense in line 2 should be senses.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-23 and 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "the first electrode" in lines 2 and 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the generally hollow electrode" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "the hollow electrode" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 recites the limitation "the first electrode" in lines 3 and 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the first electrode" in lines 2 and 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the generally hollow electrode" in line 4. There is insufficient antecedent basis for this limitation in the claim.

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Claim 21 recites the limitation "the hollow electrode" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,429,131 to Scheinman et al. Scheinman et al. discloses a catheter with proximal and distal portions with an ablation tip (electrode) on the distal end that surrounds a permanent magnetic core and further includes ring electrodes proximal to the ablation tip (Col. 7, lines 52-55). The ablation electrode is hollow and has a generally cylindrical sidewall and a domed shaped distal end (Fig. 2C). The tip of the catheter may be moved using the magnetic forces implying sufficient strength for this task. Iron (permeable material) is disclosed as an alternative magnetic material (Col. 5, lines 58-60).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,429,131 to Scheinman et al. as applied to claim 1 above and further in view of U.S. Patent

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6,015,414 to Werp et al. Scheinman et al. are discussed above, however, do not discuss the magnetic field used for control. Werp et al. teaches the use of a maximum of 0.3 Tesla (Col. 7, line 9) for a magnetically controlled catheter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the field strength as taught by Werp et al. in the device of Scheinman et al. to steer the catheter.

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,429,131 to Scheinman et al. as applied to claim 1 above and further in view of U.S. Patent 6,017,338 to Brucker et al. and further in view of U.S. Patent 6,385,472 to Hall et al. Scheinman et al. are discussed above, however, do not discuss the delivery of fluids through the electrode. Brucker et al. teach a fluid cooled tip for a catheter that uses either a sintered metal electrode which allows perfusion via many small passages (Col. 5, lines 30-35) or specifically formed apertures in the electrode (Col. 5, lines 55-61). Hall et al. disclose a magnetically navigable catheter with permanent magnets in the distal end of a flexible catheter that allow the distal end of the catheter to be oriented by the application of an externally applied magnetic field (abstract). The distal end of the catheter is disclosed as being more flexible than the rest of the catheter (abstract). Hall et al. teach delivery of fluids through the distal electrode and annular magnets (hollow center) to provide a path for a fluid lumen. The delivery of fluids via catheters is well known with multiple variations in wide use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide passages in the electrode of Scheinman et al. as taught by Brucker et al. to deliver cooling fluids or treatment agents to the tip of the catheter and provide a path for fluid delivery by a lumen through the magnet as taught by Hall et al. as fluid delivery from a catheter is pervasive in the art. The means for delivery provided by Hall et al. and Brucker et al. are representative of the state of the art.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,429,131 to Scheinman et al. as applied to claim 15 above and further in view of U.S. Patent 6,017,338 to Brucker et al. and further in view of U.S. Patent 6,385,472 to Hall et al. All are discussed above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide passages in the electrode of Scheinman et al. as taught by Brucker et al. to deliver cooling fluids or treatment agents to the tip of the catheter and provide a path for fluid delivery by a lumen through the magnet as taught by Hall et al. as fluid delivery from a catheter is pervasive in the art. The means for delivery provided by Hall et al. and Brucker et al. are representative of the state of the art.

Claims 19 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,429,131 to Scheinman et al. in view of U.S. Patent 6,015,414 to Werp et al. Scheinman et al. are discussed above, however, do not discuss the magnetic field used for control. Werp et al. teach the use of a maximum of 0.3 Telsa (Col. 7, line 9) for a magnetically controlled catheter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the field strength as taught by Werp et al. in the device of Scheinman et al. to steer the catheter.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,429,131 to Scheinman et al. in view of U.S. Patent 6,015,414 to Werp et al. as applied to claim 19 above and further in view of U.S. Patent 6,017,338 to Brucker et al. and further in view of U.S. Patent 6,385,472 to Hall et al. The delivery of fluids via catheter is well known with multiple variations in wide use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide passages in the invention of Scheinman et al. (modified by Werp et al.) as taught by Brucker et al. to deliver cooling fluids or treatment agents to the tip of the catheter and provide a path for fluid delivery by a lumen through the magnet as

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taught by Hall et al. as fluid delivery from a catheter is pervasive in the art. The means for delivery provided by Hall et al. and Brucker et al. are representative of the state of the art.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,015,414 to Werp et al. in view of U.S. Patent 5,429,131 to Scheinman et al. Werp et al. teach a method for controlling movement of a catheter through a medium, in which a flexible catheter having a magnetic tip is pushed through a medium, and a magnetic field having a magnitude and orientation effective to guide the catheter tip in a predetermined direction is applied (Col. 3, lines 43-49). Werp et al. do not disclose any specifics of the catheter except for the magnet in the distal end. Scheinman et al. are discussed above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the magnetic catheter as taught by Scheinman et al. with the methods of Werp et al. to position the catheter.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,015,414 to Werp et al. in view of U.S. Patent 5,429,131 to Scheinman et al. as applied to claim 24 above and further in view of U.S. Patent 6,017,338 to Brucker et al. and further in view of U.S. Patent 6,385,472 to Hall et al. All have been previously discussed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to catheter structure in the methods of Werp et al. (modified by Scheinman et al.) as taught by Brucker et al. to deliver cooling fluids or treatment agents to the tip of the catheter and provide a path for fluid delivery by a lumen through the magnet as taught by Hall et al. as fluid delivery from a catheter is pervasive in the art. The means for delivery provided by Hall et al. and Brucker et al. are representative of the state of the art.

Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,429,131 to Scheinman et al. in view of U.S. Patent 6,385,472 to Hall et al. Scheinman et al. discloses a catheter with proximal and distal portions with an ablation tip (electrode) on the

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distal end that surrounds a permanent magnetic core and further includes ring electrodes proximal to the ablation tip (Col. 7, lines 52-55). The ablation electrode is hollow and has a generally cylindrical sidewall and a domed shaped distal end (Fig. 2C) and has a lead wire extending proximally from the distal portion (Fig. 2C, #54A). The tip of the catheter is moved using the magnetic forces implying sufficient strength for this task. The distal tip includes a thermistor for temperature determination (Col. 7, lines 25-30). Scheinman et al. does not teach flexible sections of the catheter. Hall et al. discloses a magnetically navigable catheter with permanent magnets in the distal end of a flexible catheter that allow the distal end of the catheter to be oriented by the application of an externally applied magnetic field (abstract). The distal extension members are more flexible than the more proximal sections (Col. 3, lines 64-67). Flexibility of the Scheinman device is implicit in its use in a cardiac procedure wherein the catheter is introduced into a femoral vein and maneuvered into the atrium (Col. 2, lines 44-52) clearly teaching the importance of such flexibility. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the flexible sections as taught by Hall et al. in the invention of Scheinman to improve the maneuverability of the catheter to the target area.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,429,131 to Scheinman et al. in view of U.S. Patent 6,385,472 to Hall et al. as applied to claim 27 above, and further in view of U.S. Patent 6,056,745 to Panescu et al. Hall et al. teaches the delivery of fluids to the treatment area through the catheter (Col. 3, lines 33-35). The use of channels for fluid delivery in catheters is pervasive in the art and therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the fluid delivery means as taught by Hall et al. in the invention of Scheinman et al. to provide cooling or therapeutic agents to the treatment site. Neither Hall et al. nor Scheinman teach an opening between a sleeve and the distal tip for fluid transfer. Panescu et al. discloses a catheter

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system with an electrode for ablating body tissue that includes providing cooling by introducing fluids in an annular space between a sleeve (Fig. 3A, # 60) and the distal end of the catheter (Fig. 3A, #16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Scheinman et al. as modified by Hall et al. with the fluid transfer means taught by Panescu et al. as an equivalent alternative for fluid delivery.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,429,131 to Scheinman et al. in view of U.S. Patent 6,385,472 to Hall et al. as applied to claim 27 above, and further in view of U.S. Patent 5,729,129 to Acker. Neither Hall et al. nor Scheinman et al. teach a magnetic detection system in their devices. Acker discloses means for locating medical instruments within a body of a patient (abstract) using coils mounted as sensors in the instrument (Fig. 6). The leads for the coils are lead via a cable to the command unit (Col. 5, lines 49-53). Since the devices of both Scheinman et al. and Hall et al. are maneuvered within a body, precise position information is critical. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the locating coils of Acker in the catheter of Scheinman et al. as modified by Hall et al. to determine the exact position of the catheter tip as an alternative to fluoroscopy or other imaging techniques.

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,429,131 to Scheinman et al. in view of U.S. Patent 6,385,472 to Hall et al. as applied to claim 27 above, and further in view of U.S. Patent 6,017,338 to Brucker et al. Neither Scheinman et al. nor Hall et al. teach a plurality of openings in the electrode for fluid transfer, however Hall et al. teaches a central passage through the electrode and magnet for the delivery of agents (Col. 3, lines 33-35). Brucker et al. teaches a fluid cooled tip for a catheter that uses either a sintered metal electrode which allows perfusion via many small passages (Col. 5, lines 30-35) or specifically formed apertures in the electrode (Col. 5, lines 55-61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide

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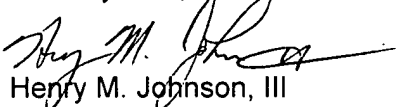
passages in the electrode of Scheinman et al. as modified by Hall et al. with the fluid transfer means taught by Brucker et al. to deliver cooling fluids or treatment agents to the tip of the catheter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Henry M. Johnson, III
Patent Examiner
Art Unit 3739